

In the United States Court of Federal Claims

**No. 05-588V
(Filed February 21, 2007)
(Not for Publication)**

**PHILLIP WAY,
as parent of his daughter,
BAILEY WAY,**

Petitioner,

v.

**SECRETARY OF HEALTH AND HUMAN
SERVICES,**

Respondent.

OPINION AND ORDER

WILLIAMS, Judge

Petitioner, Philip Way, pro se, acting on behalf of his daughter, Bailey Way, seeks review of the Special Master's dismissal of his petition for compensation under the National Childhood Vaccine Injury Act. Petitioner claims that Bailey suffered acute demyelinating encephalomyelitis (ADEM) as a result of receiving Haemophilus Influenzae type b ("Hib") or pneumococcal vaccination.¹

After obtaining six enlargements of time to submit a medical expert's opinion supporting his claim, consuming some ten months, Petitioner failed to file any expert medical opinion to establish that the vaccinations were the cause of Bailey's injury. Rather, after having been advised that no further enlargements of time would be granted, Petitioner requested a continuance of another 90 days. The Special Master denied this request, concluding that "[d]espite more than adequate

¹ ADEM is not a "Table Injury" found within 42 U.S.C. § 300aa-14(a)(2000). The treating physicians at Rockford Memorial Hospital diagnosed Bailey as having acute hemorrhagic leukoencephalopathy. Petitioner's Exhibit 2. This condition is also not a Table injury.

opportunity to submit a medical expert's opinion supporting his claim, Mr. Way has failed wholly to advance his case." Way v. Sec'y, HHS, No. 05-558, slip op. at * 8 (Fed. Cl. Spec. Mstr. Sept. 18, 2006)("Decision" or "Dec."). Further, upon review of the record, the Special Master found that Petitioner had failed to establish that the vaccine caused Bailey's injury because the "medical records alone [did] not reflect an independent basis for him to conclude more likely than not that Bailey's October 29, 2004 [Hib and pneumococcal] vaccination[s] caused-in-fact Bailey's condition. . . ." Id. at 7. As such, the Special Master dismissed the petition.

Because Petitioner failed to prove that the vaccines Bailey received were the cause-in-fact of her condition, and because the Special Master did not abuse his discretion in denying Petitioner a seventh continuance to produce an expert, the decision of the Special Master is sustained.

Factual Background²

Bailey's Medical History

Bailey Way was born on July 21, 2003. Petitioner's Exhibit 2 (Pet. Ex.) at 2. Bailey received both the Hib and pneumococcal vaccinations on October 29, 2004. Pet. Ex. 3 at 13. On October 29, 2004, when Bailey was 15 months old, Bailey's parents brought her to a pediatrician because she had been "spitting up milk" since October 26, 2004, and had "slept all day" and had been "cranky" on October 28, 2004. Pet. Ex. 3 at 28-29. The physician recommended that Bailey not be fed milk for a period of time. Id. at 29. The physician further recommended that the parents eventually try to reintroduce milk consumption, and, if that caused problems, to "try soy milk." Id.

On October 30, 2004, Bailey's mother had difficulty waking her and observed that Bailey's eyes appeared to have "rolled into the back of [her] head" and that her body was "stiff." Pet. Ex. 2 at 4. Bailey's mother called emergency services to assist Bailey. Id. Emergency personnel then took Bailey to the Beloit Memorial Hospital Emergency Room. Pet. Ex. 8 at 2; Pet. Ex. 5 at 7. At the emergency room, Bailey had a series of seizures which the doctors stopped with injections of Ativan. Pet. Ex. 5 at 8. That same day, Bailey received a lumbar puncture as part of the diagnostic process. Id. The lumbar puncture results were "abnormal." Pet. Ex. 5 at 8, 9. As a result of the findings of the lumbar puncture and other tests, the treating physician initially diagnosed Bailey with bacterial meningitis. Id. at 9, 12. Due to Bailey's neurologic status and need for higher level of care, she was transferred to Rockford Memorial Hospital on October 30, 2004. Id. at 9.

Bailey endured a complicated course of treatment and remained at Rockford Memorial Hospital for 20 days, until November 19, 2004. Pet. Ex. 2 at 3-7.³ Upon discharge, Bailey's primary

² The factual background is derived from the Special Master's decision and Petitioner's "Notice of Filing Documents, Exhibits 1-9," submitted to the Special Master on September 7, 2005.

³ Bailey was given intravenous fluids and multiple medications. Her blood and stool were tested for bacteria and toxins. She had difficulty moving her mouth and extremities, so a speech

diagnosis was acute hemorrhagic leukoencephalopathy and her secondary diagnosis was microcytic hypochromic anemia.⁴ Pet. Ex. 2 at 4. In the over 800 pages of medical records, there is no explanation why the diagnosis changed from meningitis to acute hemorrhagic leukoencephalopathy. The medical records from Rockford Memorial Hospital do not attribute a cause to Bailey's illness, noting instead that the acute hemorrhagic leukoencephalopathy was of "unknown etiology." *Id.* at 15, 96, 102.

On November 19, 2004, Bailey entered the Rehabilitation Institute of Chicago with a diagnosis of acute hemorrhagic leukoencephalopathy.⁵ Pet. Ex. 9 at 182-84; Pet. Ex. 2 at 4. Bailey was prescribed rehabilitative treatment because she continued to exhibit problems with food consumption, age appropriate communications, and general coordination and mobility. Pet. Ex. 2 at 3-7. Bailey remained in the Rehabilitation Institute of Chicago until December 23, 2004. Pet. Ex. 9 at 182. Upon discharge from the Institute, Bailey received orders for "occupational therapy, physical therapy and speech therapy." Pet. Ex. 9 at 182-84. On January 3, 2005, Bailey was seen by a physician for follow-up care at the Pediatric Gastrointestinal Clinic at Rockford Memorial Hospital. Pet. Ex. 3 at 2-3. During that visit the doctor listed Bailey's diagnosis as acute hemorrhagic leukoencephalopathy. Pet. Ex. 3 at 3.

Procedural History

Philip Way, Bailey's father, filed a petition under the National Vaccine Injury Compensation Program ("Program") with the Office of Special Masters on May 31, 2005. Dec. at 1. In the petition, Mr. Way alleged that Bailey suffers from ADEM as a result of receiving the Hib and pneumococcal vaccinations. Because the Special Master determined that the petition did not contain any of the medical, educational, or therapeutic records required for recovery under the Vaccine Act,⁶

pathologist was consulted to see if Bailey could demonstrate a "suck reflex" and swallow and consume food on her own. She could not successfully demonstrate the suck reflex or consume food on her own. On November 16, 2004, Bailey had surgery to insert a percutaneous endoscopic gastrostomy (PEG) feeding tube so that she could consume necessary nutrients. Bailey also had multiple neurologic tests, including an electroencephalogram (EEG) and a magnetic resonance imaging (MRI). She received multiple other tests to gauge her brain function, mobility, and awareness of her surroundings. Pet. Ex. 2 at 3-7. These tests occurred on an almost daily basis. Pet. Ex. 2.

⁴ According to the records, the severe microcytic hypochromic anemia was likely due to "drinking too much milk in the past." Pet. Ex. 2 at 12.

⁵ Bailey's medical records do not characterize her illness as ADEM.

⁶ Under 42 U.S.C. § 300aa-11(c), every petition shall be accompanied by the following:

(A) medical records and detailed affidavit(s) supporting all elements

he directed Petitioner to develop the documentary record. Id. at 5. In an October 4, 2005 status report, Mr. Way represented that he had filed “[a]ll medical, educational and therapeutic records [then in his possession]. . . .”⁷ Id. Because none of the exhibits submitted by Petitioner stated a cause of Bailey’s condition, the Special Master ordered the Petitioner to submit an amended petition and a medical expert’s opinion stating a cause of the illness by November 14, 2005. Id.

of the allegations made in the petition. If petitioner’s claim does not rely on medical records alone, but is based in any part on the observations or testimony of any persons, the substance of each person’s proposed testimony in the form of an affidavit executed by the affiant must accompany the petition;

(B) all available physician and hospital records relating to (i) the vaccination itself; (ii) the injury or death, including, if applicable, any autopsy reports or death certificate; (iii) any post-vaccination treatment of the injured person, including all in-patient and out-patient records, provider notes, test results, and medication records; and, (iv) if the vaccinee was younger than five years when vaccinated, the mother’s pregnancy and delivery records and the infant’s lifetime records, including physicians’ and nurses’ notes, test results, and all well-baby visit records, as well as growth charts, until the date of vaccination; and

(C) if any records required by the rules are not submitted, an affidavit detailing the efforts made to obtain such records and the reasons for their unavailability.

Rules of the United States Court of Federal Claims (RCFC), Appendix B, Vaccine Rule 2(e).

⁷ The records consisted of nine exhibits submitted to the Special Master under “Notice of Filing Documents.” The exhibits were:

Exhibit 1, Medical records from Rockford Memorial Hospital, [Rockford, IL] (Stephanie Way - pre-natal & labor & delivery); Exhibit 2, Medical records from Rockford Memorial Hospital (Bailey Way); Exhibit 3, Medical records from Rockford Clinic - Alpine; Exhibit 4, Medical records from Swedish American Medical Group; Exhibit 5, Medical records from Beloit Memorial Hospital; Exhibit 6, Medical records from Rebound Physical Therapy; Exhibit 7, Medical records from Easter Seals - Childrens Development Center; Exhibit 8, Medical records from South Beloit Fire Department - EMS Dept; Exhibit 9, Medical records from Rehabilitation Institute of Chicago.

On November 17, 2005, Mr. Way informed the Special Master that Mr. Way's "original choice for a medical expert" could not "offer an opinion" because of "health reasons." Dec. at 5. Mr. Way indicated that he had "engaged a new medical expert" and requested "an enlargement of 45 days to submit an amended petition and medical expert opinion." Id. The Special Master granted the request and directed the submission of an amended petition and a medical expert's opinion supporting the amended petition by no later than January 6, 2006. Id.

On January 6, 2006, Mr. Way informed the Special Master that Petitioner's expert had "submitted a draft report" to Petitioner's attorney and that the attorney and the expert were "working on a final report." Dec. at 5-6. Mr. Way requested "an enlargement of 30 days to submit an amended petition and medical expert opinion." Id. at 6. The Special Master granted the request and directed the submission of an amended petition and a medical expert's opinion supporting the amended petition by no later than February 8, 2006. Id. Mr. Way subsequently requested, and was granted by the Special Master, three additional enlargements of time to submit an amended petition and medical expert's opinion on February 13, 2006, March 13, 2006, and May 8, 2006.⁸ Id.

In the May 8, 2006 order granting Petitioner's enlargement request, the Special Master directed that Petitioner submit an amended petition and a medical expert's opinion supporting the amended petition by June 9, 2006. Dec. at 6. Mr. Way failed to comply. Instead, on June 16, 2006, Mr. Way's attorney moved to withdraw his appearance. Id. On June 20, 2006, the Special Master granted the attorney's Motion to Withdraw. Id.

On June 21, 2006, the Special Master issued an order to show cause, stating:

[t]he statute governing the Program prohibits the special master from awarding compensation 'based on the claims of a petitioner alone' The special master has canvassed thoroughly the record [and] determines that Bailey's medical records alone do not reflect an independent basis . . . to conclude more likely than not [the vaccinations caused the injury] [D]espite adequate opportunity, Mr. Way [has] not produced yet a medical expert's opinion supporting the case.

Order to Show Cause at 2, June 21, 2006. The Special Master directed Mr. Way to file by no later than July 21, 2006, an amended petition and a medical expert's opinion, as the Special Master had

⁸ In the February 13, 2006 request, Mr. Way stated that his expert had "formulated a preliminary opinion" and that he needed time for his counsel and expert to discuss the opinion. Dec. at 6. In the March 13, 2006 request, Mr. Way stated that his expert was not able to finalize his opinion because of "obligations associated with his clinical practice." Id. In the May 8, 2006 request, Mr. Way stated that he was working with his expert to develop a medical theory and conducting research. Id.

“required in numerous previous orders,” or to “show cause why the special master should not dismiss the petition.” Id.

On July 12, 2006, Mr. Way requested a continuance for 60 days to respond to the show cause order. Mr. Way stated that he was awaiting receipt of the case file from his previous attorney. Dec. at 7. According to Mr. Way, he required additional time “to seek the necessary medical expert’s opinion.” Id. The Special Master granted Mr. Way’s continuance, enlarging to September 15, 2006, the time within which Mr. Way could either file an amended petition and a medical expert’s opinion, or show cause why the Special Master should not dismiss the petition. Id. This order stated that “the special master does not contemplate any further enlargements of time.” Id. Nonetheless, on September 12, 2006, Mr. Way requested a continuance of 90 days to file the medical expert’s opinion stating that the “records and notes are numerous and this review requires the time and availability of the physicians. I am subject to their schedule.” Pet. Enlargement Request, (Sept. 12, 2006).

On September 18, 2006, the Special Master denied Mr. Way’s September 12, 2006 request stating:

Despite more than adequate opportunity to submit a medical expert’s opinion supporting his claim, Mr. Way has failed wholly to advance his case. On the record before him, the special master determines that Mr. Way is not entitled to Program compensation. In the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

Dec. at 8.

On October 16, 2006, Mr. Way petitioned this Court to review the Special Master’s decision dismissing the claim for vaccine compensation, and on November 15, 2006, the Secretary of Health and Human Services responded.

Discussion

Jurisdiction and Standard for Review

This Court “shall . . . have jurisdiction over proceedings to determine if a petitioner under . . . 42 U.S.C. § 300aa-11 is entitled to compensation under the Program and the amount of such compensation. . . .” 42 U.S.C. § 300aa-12 (2000). Upon the filing of a petition,

the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter--

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction. . . .

42 U.S.C. § 300aa-12(e)(2)(A)-(C); see Althen v. Sec'y of HHS, 418 F.3d 1274, 1277 (Fed. Cir. 2005); Saunders v. Sec'y of HHS, 25 F.3d 1031, 1033 (Fed. Cir. 1994). The Court of Federal Claims must uphold a special master's findings of fact and conclusions of law unless the Court determines that they are arbitrary or capricious, an abuse of discretion, or otherwise not in accordance with law. See 42 U.S.C. § 300aa-12(e)(2)(B); see also Munn v. Sec'y of HHS, 970 F.2d 863, 870 (Fed. Cir. 1992) (noting that the arbitrary and capricious standard is "well understood to be the most deferential possible"). A decision is arbitrary and capricious if it relied on factors which Congress has not intended, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence, or is so implausible that it could not be ascribed to a difference in view. Motor Vehicle Mfrs. Assn. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); Hines v. Sec'y of HHS, 940 F.2d 1518, 1527 (Fed. Cir. 1991). Reversible error is "extremely difficult to demonstrate" if the special master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision." Hines, 940 F.2d at 1527. As the Federal Circuit recognized, "it is not . . . the role of [a] court [reviewing a special master's decision] to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence." Lampe v. Sec'y of HHS, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (citing Munn, 970 F.2d at 871). Nor should this Court "examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder." Id.

Burden of Proof

Petitioner is representing himself in this matter. "A pro se party's allegations, 'however inartfully pleaded,' will be held to 'less stringent standards' than formal allegations drafted by lawyers." Wiley v. United States, 69 Fed. Cl. 733, 735 (2006)(quoting Haines v. Kerner, 404 U.S. 519, 520, reh'g denied, 405 U.S. 948 (1972)). "A pro se party's allegations will only be dismissed before giving the plaintiff an opportunity to present evidence if it appears 'beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" Id. (quoting Conley v. Gibson, 355 U.S. 41, 45-46 (1957)).

Recovery under the Vaccine Act may be established in one of two ways, through a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury

Table (Table), or, where the injury is not listed in the Table, by proving causation-in-fact. See 42 U.S.C. §§ 300aa-11 (c)(1)(C), -13(a)(1); 42 U.S.C. § 300aa-14. Causation of injury due to a vaccine is presumed if a petitioner supports, with medical records or expert testimony, a claim of an injury listed on the Table, 42 U.S.C. § 300aa-14(a), and shows by a preponderance of the evidence that the injury occurred within the time period described by the Table. 42 U.S.C. § 300aa-13(a)(1)(A). However, ADEM is not listed on the Table; nor is acute hemorrhagic leukoencephalopathy. See 42 U.S.C. § 300aa-14(a). As a result, Petitioner had the obligation to prove that the vaccinations were the cause-in-fact of Bailey's contracting ADEM or acute hemorrhagic leukoencephalopathy. See Althen, 418 F.3d at 1278.

Causation-in-fact requires a petitioner to prove by a preponderance of evidence that a vaccine caused the alleged injury. Compensation for non-Table injuries is authorized under 42 U.S.C. § 300aa-11(c)(1), and includes any "illness, disability, injury, or condition" not listed on the Table, or not meeting the Table's requirements. See 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii)(I)-(II). Causation-in-fact is established under a traditional tort analysis. See Althen v. Sec'y of HHS, 58 Fed. Cl. 270, 280 (2003) aff'd, 418 F.3d 1274 (Fed. Cir. 2005). A petitioner may recover if he or she shows "'that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" Althen, 418 F.3d at 1278 (quoting Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)). To recover, scientific certainty that a vaccination caused an injury is not required. Bunting v. Sec'y of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991).

The Vaccine Act states:

(1) Compensation shall be awarded under the [Vaccine Injury] Program to a petitioner if the special master or court finds on the record as a whole-

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term 'factors unrelated to the administration of the vaccine'--

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma . . . , or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

42 U.S.C. § 300aa-13(a).

This statutory scheme establishes that the burden is initially on the petitioner to prove a prima facie case by a preponderance of the evidence. If a petitioner establishes a prima facie case, the burden shifts to the respondent to prove by a preponderance of the evidence that the petitioner's injury was caused by an unrelated factor. See Althen, 418 F.3d at 1278; De Bazan v. Sec'y of HHS, 70 Fed. Cl. 687, 693 (2006); Paulmino v. Sec'y of HHS, 69 Fed. Cl. 1, 11-12 (2005). As the Federal Circuit recently articulated, to show causation-in-fact, the petitioner must prove:

(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) . . . a proximate temporal relationship between the vaccination and injury.

Pafford v. Sec'y of HHS, 451 F.3d 1352, 1355 (Fed. Cir. 2006)(citations omitted). If a petitioner "satisfies this burden, she is 'entitled to recover unless the [Government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.'" Althen, 418 F.3d at 1278 (quoting Knudsen v. Sec'y of HHS, 35 F.3d 543, 547 (Fed. Cir. 1994)). "The shifting burdens of production and proof provided by the Vaccine Act are particularly important when dealing with an area of medical science that is as poorly understood as ADEM and where there is admitted uncertainty as to causation among medical experts." De Bazan, 70 Fed. Cl. at 693.

The Special Master Properly Determined That Petitioner Did Not Prove Causation-in-Fact

Petitioner has failed to establish a prima facie case that the Hib and pneumococcal vaccinations were the cause-in-fact of Bailey's injury. Even accepting that there may be a medical theory causally connecting these vaccines with Bailey's claimed injury and that there may be a proximate temporal relationship between the vaccines and some injury, there is no suggestion in the medical records of a logical sequence of cause and effect showing that the vaccinations were the reason for Bailey's injury. Rather, the medical records documented Bailey's acute hemorrhagic leukoencephalopathy as having an "unknown etiology." Pet. Ex. 2 at 15, 96, 102; Pet. Ex. 3 at 2.

Because there is no indication in any of the medical records that the vaccinations may have caused Bailey's injuries, Petitioner has failed to prove a logical sequence of cause and effect.

The Special Master Did Not Err In Denying Petitioner the 90-day Continuance

Because the medical records were devoid of evidence of a "logical sequence of cause and effect showing that the vaccine was the reason" for Bailey's injury, the Special Master properly directed Petitioner to file an expert opinion. Pafford, 451 F.3d at 1355. Petitioner failed to comply with the Special Master's orders after receiving six enlargements of time and some 10 months to do so, and after being warned that no further extensions would be granted. As such, the Special Master's denial of yet another continuance was reasonable and not an abuse of discretion. See 42 U.S.C. § 300aa-12(d)(3)(C). Under the Vaccine Act, special masters are directed to conduct proceedings in an expeditious fashion. The Act provides:

The special master shall determine the nature of the proceedings with the goal of making the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case and creating a record sufficient to allow review of the special master's decision.

RCFC Appendix B, Rule 3(b); 42 U.S.C. §§ 300aa-12(d)(3)(B)(i)-(v). By statute, "[t]he decision of the special master shall . . . be issued as expeditiously as practicable but not later than 240 days . . . after the date the petition was filed." 42 U.S.C. § 300aa-12(d)(3)(A)(ii). Here, the Special Master granted Petitioner six continuances, a timeframe spanning more than ten months and exceeding his statutory mandate of 240 days for resolving the case.

While the Vaccine Act does not require that a petitioner submit an expert opinion in order to prevail, the Act prohibits a Special Master from awarding compensation "based upon the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1)(emphasis added). Petitioner's claims in this case are wholly unsubstantiated by medical records or expert opinion. As such, the Special Master could not have awarded compensation. Further, Vaccine Rule 21(b) expressly authorizes an involuntary dismissal "for the failure of the petitioner to prosecute or comply with the Vaccine Rules or any order." RCFC App. B, Rule 21(b). Because petitioner failed both to prosecute his case and to comply with numerous orders of the Special Master, the petition was properly dismissed.

Conclusion

1. The Special Master's decision was in accord with the Vaccine Act and was not arbitrary, capricious, or an abuse of discretion. See 42 U.S.C. § 300aa-12(e)(2). The Special Master's dismissal is sustained.

2. The Clerk shall not disclose this decision publicly for 14 days.

s/Mary Ellen Coster Williams
MARY ELLEN COSTER WILLIAMS
Judge